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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: Comments on Proposed Amendments to 21 CFR parts 1010 and 1040.

Docket No. 93N-0044.

Harmonization of the CDRH laser regulations with those of the IEC 825-1 would be very helpful in bringing products to market efficiently, cost effectively, and with a uniform set of classification and label requirements which serve the global marketplace as well as end user understanding and safety. In this regard, this harmonization effort should perhaps evolve more concurrently. Apparently IEC 825-1 has a proposed amendment under review as IEC document 76/196/CDV; it might be more effective to wait to consider this proposal rather than harmonize CDRH to a standard that may change in the near future.

The inclusion of LED's in the standard has long been an area of disagreement, if there is no known risks associated with these devices then it doesn't seem logical to include them in a harmonized standard either. Unnecessary inclusion of LED's could result in a significant and perhaps unnecessary increase in certification costs. The CDRH document includes reference to LED's in Table 7, it may have been an oversight since there are no LED references anywhere else in the proposed amended text.

In certifying equipment under both the current CDRH and IEC documents the following areas are often not clearly understood and perhaps should be re-addressed in future harmonization efforts or special application publications/guides:

- 1) How conditions of operation, maintenance, service, or single failure are to be considered in the classification scheme. A table which indicates which conditions are applicable to classification and which are applicable to labeling requirements, etc. might be helpful.
- 2) An example or procedure to be used for single failure analysis which includes mechanical, electrical, or software failure examples.
- 3) An example of the conditions and set-ups necessary using the 5 diopter lens, how the acceptance angle is determined, and under what conditions a lens is not required.
- 4) If LED's are included in the harmonized standard, an indication of how one calculates the limits and measures the power based on the fact that these sources are not as narrow spectrally as laser sources.

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- 5) Additional specifics regarding when a measurement using a 50 mm diameter aperture at 2 meters is to be used rather than a 7 mm aperture at 100 mm. A 50 mm diameter aperture is generally not available on a laser power meter but is more typical as the input port to an integrating sphere on a spectroradiometer. Measurements at 100 mm of divergent beams with such a sphere/spectroradiometer device can result in large errors due to radiation not hitting the internal baffle first prior to hitting the internal sphere walls. It may be possible to greatly simplify measurements, errors, and data analysis by using a simple laser power meter with a 7 mm diameter aperture whenever possible for either LED or laser power measurements at close distances as proposed.
- 6) Examples or methods to determine the apparent source location for convergent, divergent, and parallel beams and what the appropriate measurement distance and calculations are when the apparent source location is internal or external to the device.
- 7) How does one determine the measurement distance for classification purposes as well as the AEL when there may be multiple sources at different wavelengths and different apparent source locations?
- 8) A method to determine alpha or the 1/e points for irregularly shaped or multiple source geometries.
- 9) Does one always use the time basis applicable to the class or in what case is the actual exposure time for the application more appropriate. Specifically discuss how one calculates the class when a specific exposure time is intended for an ophthalmic exam which is different than the time basis for the class.
- 10) Greater clarity with respect to pulsed sources and how to do the calculation comparisons against the class limits.

It is the hope that these general comments might be helpful in future committee activities. Thank you for the opportunity to provide inputs to your efforts.

Sincerely,



Teresa Motz West
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cc:

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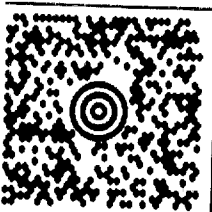
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